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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,472	04/15/2004	Robert H. Zimmer	98204.00024	8345

7590 05/15/2007

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EXAMINER	
TELLER, ROY R	
ART UNIT	**PAPER NUMBER**
1654	

MAIL DATE	DELIVERY MODE
05/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,472	ZIMMER, ROBERT H.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: Notice to comply

DETAILED ACTION

This office action is in response to the amendment, received 3/2/07, in which applicant added new claim 25.

This application contains claims 18-24, drawn to an invention nonelected. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-17 and 25 are under examination.

Response to Amendments/ Arguments

Applicant's arguments and amendments filed 3/2/07 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Sequence Compliance

Applicant is advised that the application is not in compliance with 37 CFR §§ 1.821-1.825.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR §§ 1.821- 1.825) in order to effect a complete response to this office action.

Specifically, Claim 5 recites a sequence embraced by the sequence rules.

Claim Objections

Claims 1 and 25 are objected to because of the following informality: The claims are not in compliance with 37 CFR § 1.75(i) which states, "Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-17 and 25 are/stand rejected under 35 USC 112, first paragraph for the reasons of record which are restated below.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed tothe Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register,

Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicants arguments were carefully considered but were not found persuasive. Applicant contends that, generally, the more sophisticated that a person of skill in the art would be, the less disclosure is necessary to satisfy the written description requirement. Further, there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed.

However, the examiner contends that the present claim encompasses numerous species that are not further described and that there is substantial variability among the species. Absent further disclosure from applicant, a written description rejection is appropriate.

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention.

In the instant case, the claims are drawn to a pharmaceutical agent having the formula: Carrier-Linker-Peptide.

(1) Level of skill and knowledge in the art:

The level of skill to practice the art of the instantly claimed invention is high with regard to conception, synthesis, and experimental protocols and data analysis of experimental results.

(2) Partial structure: (3) Physical and/or chemical properties: and (4) Functional characteristics:

Wherein the peptide is a peptide having the formula aa_n , wherein peptide is Tyr-Gly-Gly-Phe-Met, carrier is a cinnamoyl and derivatives thereof and wherein the linker is –C6 or C8 acididic

moiety and derivatives thereof.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus, i.e., the genus of a pharmaceutical agent having the formula : carrier-linker-peptide, wherein the peptide is a peptide having the formula aa_n , wherein peptide is Tyr-Gly-Gly-Phe-Met, carrier is a cinnamoyl and derivatives thereof and wherein the linker is –C6 or C8 acididc moiety and derivatives, pseudopeptides, and peptide mimics thereof.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for

obtaining the claimed chemical invention".

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.* wherein peptide is Tyr-Gly-Gly-Phe-Met, carrier is a cinnamoyl and wherein the linker is –C6 or C8 acididc moiety. The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species of derivatives, pseudopeptides, peptide mimics, and pharmaceutical agents with an immune sequence characteristic of an infectious, viral or cancerous disease that are not further described and there is substantial variability among the species. No single claim is drawn to a single species which is fully defined.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises the genus of derivatives of the carrier and the linker. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

All other claims depend directly or indirectly from the rejected claim and are, therefore, also rejected under 35 USC 112, first paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Bodor (US 5624894).

The instant invention is drawn to a pharmaceutical agent having the formula: carrier-linker-peptide.

Bodor discloses novel peptide derivatives which are designed to deliver pharmacologically active peptides (ranging from 2 to 20 amino acids in length) into the central nervous system, see Abstract. These pharmacologically active peptides are modified by linking a dihydropyridine-type redox moiety via an amino acid linker. Bodor also discloses that acyl group such as benzoyl and phenylacetyl are used to protect OH group(s) during synthesis and/or to improve lipoidal (lipid-soluble or lipophilic) characteristics and to prevent premature metabolism of the OH group(s) prior to the compound's reaching the desire site in the body. See col. 14, lines 42-65; col. 18, lines 15-33; col. 19, lines 23-29; claim 1, col. 180, lines 50-55; claim 17, col. 182, line 2.

Therefore, the reference is deemed to anticipate the instant claims above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 7 and 9-14 of U.S. Patent No.6,908,900. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention is drawn to a pharmaceutical agent having the formula : carrier-linker-peptide, wherein the peptide is a peptide having the formula aa n , wherein peptide is Tyr-Gly-Gly-Phe-Met, carrier is a cinnamoyl and wherein the linker is –C6 or C8 acididc moiety.

The '900 patent is drawn to a pharmaceutical agent comprising a carrier moiety and a peptide species, wherein the carrier moiety is chemically linked to the peptide, wherein the peptide comprises Tyr-Gly-Gly-Gly-Phe-Met and wherein the carrier is cinnamoyl. The linker

species is directly bound to the carrier. Alternatively, the linker species is bound to the carrier through a –C6 or-C8 acidic moiety. More preferably, the linker speies is Gly-carba-Gly, a pseudo-peptide. See, i.e, for example, abstract, column 2, lines 29-65, column 6, lines 54-60, and claims 1, 3, 7, and 9-14.

Claims 1-17 and 25 are directed to an invention not patentably distinct from claims 1, 3, 7, and 9-14 of commonly assigned USPN 6,908,900. Specifically, Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention is drawn to a pharmaceutical agent having the formula : carrier-linker-peptide, wherein the peptide is a peptide having the formula aa n , wherein peptide is Tyr-Gly-Gly-Phe-Met, carrier is a cinnamoyl and wherein the linker is –C6 or C8 acididc moiety.

The '900 patent is drawn to a pharmaceutical agent comprising a carrier moiety and a peptide species, wherein the carrier moiety is chemically linked to the peptide, wherein the peptide comprises Tyr-Gly-Gly-Gly-Phe-Met and wherein the carrier is cinnamoyl. The linker species is directly bound to the carrier. Alternatively, the linker species is bound to the carrier through a –C6 or-C8 acidic moiety. More preferably, the linker speies is Gly-carba-Gly, a pseudo-peptide. See, i.e, for example, abstract, column 2, lines 29-65, column 6, lines 54-60, and claims 1, 3, 7, and 9-14.The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned USPN 6,908,900, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the

examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT
1654
5/9/07
RT

Andrew O'Kosar 5/11/07
ANDREW D. KOSAR, Ph.D.
PATENT EXAMINER
TC 1600

Notice to Comply	Application No.	Applicant(s)
	10/825,472	Zimmer
	Examiner	Art Unit
	Teller	1654

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: [redacted]

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.**

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
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